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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,532	12/21/2001	Szu-Min Lin	ASP0054USC1P2	5937

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	PAPER NUMBER
1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/029,532	LIN, SZU-MIN	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This non-final action is in response to the amendment received on 2/19/2008

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 22 and 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Lin (U.S.P.N. 5,834,313)

3. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 22, Lin discloses a modular sterilization assembly (the entire device shown in figure 7) for sterilizing an item, the assembly comprising: a first module (figure 7:160, 104, 164, and 126) that is capable of defining a sterile enclosure, the first module (160, 104, 164, and 126) comprising: an inlet port (unlabeled opening covered

with permeable membrane 164); an outlet port (unlabeled bottom opening of 126); a first barrier for covering the inlet port (permeable membrane164), wherein the first barrier comprises a vapor permeable, microorganism impermeable material (Lin teaches, col.5, lines 1-4, placing biological indicators into a gas permeable/microorganism impermeable package and further teaches such material, 128, on the bottom of cartridge holder 126 such that one of ordinary skill in the art would readily recognize that the internal volume within the first module needs to be maintained in a clean and sterile conditions in order to obtain the sterility of the treated items within the first module); and a second barrier for covering the outlet port (128), wherein the second barrier comprises a vapor permeable, microorganism impermeable material (col.5, lines 14-16); and a second module (figure 7:150) that is capable of being attached to and detached (col.7, lines 41-42) from the first module (160, 104, 164, and 126), the second module comprising: a sterilant (figure 7:118); and an opening (figure 7:162), wherein the opening is configured to be placed in fluid communication with the inlet port (164).

As to claim 24, Lin discloses a third module (unlabeled cartridge present within cartridge holder 126 in figure 7) that is capable of being attached to and detached from (col.4, lines 58-59) the first module (160, 104, 164, and 126).

As to claim 25, Lin discloses that the first module further comprises a baffle (unlabeled rack within unlabeled sterilization container in figure 7) that lengthens the flow path (vapor upon going through inlet port, unlabeled opening covered with164, has to go into the perforated walls of the unlabeled rack and also has to travel around the

rack before exiting through outlet port, unlabeled bottom opening of 126, of the sterilant between the inlet port and the outlet port.

Regarding claim 26, Lin in a different embodiment teaches that the second module (unlabeled cartridge that is removable from housing 126 in figure 1C) where this second module further comprises an indicator (figure 1C:124 and 122) and wherein the indicator is configured to indicate a level of sterilization (col.4, lines 62-65) achieved in the first module.

Regarding claim 27, Lin in a different embodiment teaches that the opening (unlabeled opening at 155 in figure 6A) of the second module (figure 6A:150 and 151) is a first opening, wherein the second module further comprises a second opening (unlabeled opening of connector 151 that is connected to opening 152 in figure 6A), and wherein the second opening is configured to be placed in fluid communication (through opening 152) with the outlet port (unlabeled opening of cartridge 124 in figure 6A).

Regarding claim 28, Lin teaches a third barrier (figure 6A:158) for covering the second opening (unlabeled opening of connector 151 that is connected to opening 152 in figure 6A), wherein the third barrier comprises a vapor permeable, microorganism impermeable material (col.7, lines 6-8).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 29, 31-36, and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (U.S.P.N. 5,834,313) in view of Childers et al (U.S.P.N. 5,556,607).

Regarding claim 29, Lin discloses a modular sterilization assembly (the entire device shown in figure 7) for sterilizing an item, the assembly comprising: a first module (figure 7:160, 104, 164, and 126) that is capable of defining a sterile enclosure, the first module (160, 104, 164, and 126) comprising: an inlet port (unlabeled opening covered with permeable membrane 164); an outlet port (unlabeled bottom opening of 126); a first barrier for covering the inlet port (permeable membrane164), wherein the first barrier comprises a vapor permeable, microorganism impermeable material (Lin teaches, col.5, lines 1-4, placing biological indicators into a gas permeable/microorganism impermeable package and further teaches such material, 128, on the bottom of cartridge holder 126 such that one of ordinary skill in the art would readily recognize that the internal volume within the first module needs to be maintained in a clean and sterile conditions in order to obtain the sterility of the treated items within

the first module); and a second barrier for covering the outlet port (128), wherein the second barrier comprises a vapor permeable, microorganism impermeable material (col.5, lines 14-16); and a second module (figure 7:150) that is configured to be engaged (through fluid communication) with the inlet port (unlabeled opening covered with permeable membrane 164) and the outlet port (unlabeled bottom opening of 126), the second module comprising: a sterilant (figure 7:118); and an opening (figure 7:162). Lin fails to teach that the second module is configured to circulate the sterilant into the first module and back into the second module.

Childers discloses a second module (for example, 112 in figure 11) that is capable of circulating (vapor enters second module 112 through inlet 122 and exits through outlet 124 into first module 110 in figure 112) the sterilant into the first module (for example, 110 in figure 11) and back into the second module (figure 11:112), because this device ensures contact between the sterilant and the hard to reach lumens and cervices of medical, surgical and dental tools (col.1, lines 65-67 and col.2, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the assembly in Lin with the second module having an inlet and an outlet, because such a device ensures contact between the sterilant and the hard to reach lumens and cervices of medical, surgical and dental tools as explained by Childers (col.1, lines 65-67 and col.2, lines 1-2).

Regarding claim 35, Lin discloses a modular sterilization assembly (the entire device shown in figure 7), comprising: a first module (figure 7:160, 104, 164, and 126) configured to receive an item to be sterilized; and a second module(figure 7:150)

including a sterilant (118), wherein the first module is configured to be placed in fluid communication (162) with the second module, and wherein the second module is capable of being attached to and detached (col.7, lines 41-43) from the first module. Lin fails the kind of attachment for the second module.

Childers discloses a second module (for example, 112 in figure 11) that is attached and detached from the first module (for example, 110 in figure 11) through a snap configuration (figure 11:120, 170, 190, 360, and 250) in order to lock the cassette into position to maintain the fluid connections during operation and to prevent inadvertent removal of a cassette during processing (col.7, lines 39-43). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the assembly in Lin with the snap configuration in order to lock the cassette into position to maintain the fluid connections during operation and to prevent inadvertent removal of a cassette during processing as explained by Childers (col.7, lines 39-43).

Regarding claim 39, Lin teaches a method of sterilizing an item (col.1, lines 6-8), comprising: receiving the item (col.2, lines 62-63) in a first module (figure 8:100); sealing the first module (100) with a vapor permeable, microorganism impermeable material (figure 8:128, unlabeled barrier in connector 151, col.5, lines 5-6, lines 14-18, and col.7, lines 5-10); removably attaching a second module (figure 8:150 and col.6, lines 63-65) to the first module (100), wherein the second module (150) includes a sterilant (118); flowing the sterilant into the first module; and detaching the first module from the second module (col.7, lines 7-10) while maintaining the item in a sterile

condition within the first module. Lin fails to teach flowing the sterilant back into the second module.

Childers discloses a second module (for example, 110 in figure 11) that is connected to a first module (for example, 112 in figure 11) where the vapor sterilant is flown back from the first module (112) into the second module (110) through outlet orifice (124), because such a device ensures contact between the sterilant and the hard to reach lumens and cervices of medical, surgical and dental tools (col.1, lines 65-67 and col.2, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Lin with a sterilant-flowing back step into the second module, because such a device ensures contact between the sterilant and the hard to reach lumens and cervices of medical, surgical and dental tools as explained by Childers (col.1, lines 65-67 and col.2, lines 1-2).

As to claim 31, Lin discloses a third module (unlabeled cartridge present within cartridge holder 126 in figure 7) that is capable of being attached to and detached from (col.4, lines 58-59) the first module (160, 104, 164, and 126).

As to claim 32, Lin discloses that the first module further comprises a baffle (unlabeled rack within unlabeled sterilization container in figure 7) that lengthens the flow path (vapor upon going through inlet port, unlabeled opening covered with164, has to go into the perforated walls of the unlabeled rack and also has to travel around the rack before exiting through outlet port, unlabeled bottom opening of 126, of the sterilant between the inlet port and the outlet port.

Regarding claim 33, Lin teaches in a different embodiment that the second module (unlabeled cartridge that is removable from housing 126 in figure 1C) where this second module further comprises an indicator (figure 1C:124 and 122) and wherein the indicator is configured to indicate a level of sterilization (col.4, lines 62-65) achieved in the first module.

As to claim 34, Lin teaches in a different embodiment that the first module further comprises rounded comers (figure 9A:200), and wherein the rounded comers are capable of providing for more efficient flow of the sterilant within the first module (200).

Regarding claim 36, Lin discloses in another embodiment that the first module (figure 8:100) further comprises a first inlet port (unlabeled opening in the first module where connector 151 is positioned) and a first outlet port (upon removing cartridge 120, the gas barrier 128 is considered the first outlet port since), and wherein the second module (figure 8:150) further comprises a second inlet port (unlabeled part of connector 151 that is connected to first module 100 in figure 8), a second outlet port (unlabeled part of connector 151 that is connected to second module 150 in figure 8), and a fan (figure 8:160) that is capable of circulating the sterilant between the first module (100) and the second module (150).

Regarding claim 38, Lin discloses that the first module further comprises a baffle (unlabeled rack within unlabeled sterilization container in figure 7) that lengthens the flow path (vapor upon going through inlet port, unlabeled opening covered with164, has to go into the perforated walls of the unlabeled rack and also has to travel around the rack before exiting through outlet port, unlabeled bottom opening of 126, of the sterilant

between the first inlet port and the first outlet port.

Regarding claim 40, Lin teaches sealing an inlet port (unlabeled gas permeable, microorganism impermeable barrier present in unlabeled port of first module 100 in figure 8 where the barrier is in communication with connector 151 and col.7, lines 6-9) and an outlet port (unlabeled opening covered with gas permeable, microorganism impermeable 128).

Regarding claim 41, Lin teaches in another embodiment flowing the sterilant into a third module (the unlabeled indicator cartridge that is placed within cartridge holder 126 in figure 7).

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (U.S.P.N. 5,834,313) as applied to claim 22 and further in view of Cicirello (U.S.P.N. 3,576,593).

Lin fails to teach placing the fan in a separate module that is removable from the second module. Cicirello uses a removable modular fan structure (figure 5:12) in order to simplify the process of changing fans (column 2, lines 42-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the assembly in Lin with a removable modular fan structure in order to simplify the process of changing fans as explained by Cicirello (column 2, lines 42-44).

8. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (U.S.P.N. 5,834,313) in view of Childers et al (U.S.P.N. 5,556,607) as applied to claim 29 and further in view of Cicirello (U.S.P.N. 3,576,593).

Lin and Childers fail to teach placing the fan in a separate module that is removable from the second module. Cicirello uses a removable modular fan structure (figure 5:12) in order to simplify the process of changing fans (column 2, lines 42-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified assembly in Lin/Childers with a removable modular fan structure in order to simplify the process of changing fans as explained by Cicirello (column 2, lines 42-44).

9. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (U.S.P.N. 5,834,313) in view of Childers (U.S.P.N. 5,556,607) as applied to claim 36 and further in view of Kaye (U.S.P.N. 4,410,492).

Lin and Childers fail to teach that a portion of the enclosure is configured to be engaged with a portion of a lumen device such that the sterilant is configured to flow into the enclosure, through an aperture in the lumen device, and into the first module. Kaye discloses that a portion (figure 1:22) of the enclosure (figure 1:11) is configured to be engaged with a portion of the lumen device (figure 1:23, 24, and 22) in order to maintain the sterilant gas within the lumen of the apparatus for an effective period of time (col.1, lines 16-19). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified assembly in Lin/Childers with an engaging portion that is part of the enclosure in order to maintain the sterilant gas within the lumen of the apparatus for an effective period of time as explained by Kaye (col.1, lines 16-19).

Response to Arguments

10. Applicant's arguments with respect to claims 22-41 have been considered but are moot in view of the new ground(s) of rejection.

The amendment to the specification submitted on 02/19/2008 has been accepted.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. R. C./

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797